UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,477	08/24/2001	Andrew William Heath	2257-1-001CON	1891

23565 7590 10/02/2003

KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,477	HEATH, ANDREW WILLIAM	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply .

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 April 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment, filed 4/17/02, has been entered.
Claim 22 has been amended.
Claim 23 has been added.

2. Claims 1-23 link Inventions I-XII. The restriction requirement the linked inventions is subject to the nonallowance of the linking claim(s), claims 2, 15, 17, 22 and 23. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Prior to setting forth the restriction requirement, it is pointed out that the claims are drawn to patentably distinct methods and products. The claimed products and methods upon anti-CD40 antibodies and CD40 ligand, which differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. The examiner notes that these molecules do not share a substantial structural feature essential to a common utility. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, drawn to an adjuvant as it reads on anti-CD40 antibodies, classified in Class 424, subclass 130.1.

II. Claims 1-, drawn to an adjuvant as it reads on CD40 ligand, classified in Class 514, subclass 8.

III. Claims 2-14, drawn to a vaccine comprising a T cell-dependent /-independent antigen and an adjuvant which is anti-CD40 antibody, classified in Class 424, subclass 184.1.

IV. Claims 2-14, drawn to a vaccine comprising a T cell-dependent /-independent antigen and an adjuvant which is CD40 ligand, classified in Class 424, subclass 184.1.

V. Claims 15-16, drawn to a method of manufacture of a vaccine wherein the adjuvant is anti-CD40 antibody, classified in Class 435, subclass 69.1.

VI. Claims 15-16, drawn to a method of manufacture of a vaccine where the adjuvant is CD40 ligand, classified in Class 435, subclass 69.1.

VII. Claims 17-21, drawn a system of manufacture, wherein the adjuvant is anti-CD40 antibody , classified in Class 435, subclass 440

Applicant is invited to clarify the meaning or metes and bounds of the claimed system.

VIII. Claims 17-21, drawn a system of manufacture, wherein the adjuvant is CD40 ligand, classified in Class 435, subclass 440

Applicant is invited to clarify the meaning or metes and bounds of the claimed system

IX Claim 22, drawn to a nucleic acid encoding an adjuvant which is anti-CD40 antibody, classified in Class 536, subclass 23.5.

X Claim 22, drawn to a nucleic acid encoding an adjuvant which is CD40 ligand, classified in Class 536, subclass 23.1.

XI. Claim 23, drawn to a nucleic acid encoding a vaccine an adjuvant which is anti-CD40 antibody, classified in Class 536, subclass 23.4.

XII. Claim 23, drawn to a nucleic acid encoding a vaccine an adjuvant which is CD40 ligand, classified in Class 536, subclass 23.4.

3. Inventions I/II/IV/VII/VII /IX/X/XI/XII are different products. Adjuvants, vaccines, nucleic acids encoding adjuvants, nucleic acids encoding vaccines and systems of manufacture are distinct because their structures and modes of action are different. Anti-CD40 antibodies and CD40 ligand differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. The examiner notes that these molecules do not share a substantial structural feature essential to a common utility. Therefore, they are patentably distinct.

4. Inventions (V and III) and (VI and IV) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)).

In the instant case, the claimed vaccines can be made via a variety of recombinant and biochemical means.

5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-XII is not required for any other group from Groups I-XII and Groups I-XII have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed Invention III-XII: wherein the vaccine comprises:

A) a T cell-independent antigen or

B) a T cell-dependent antigen.

These species are distinct because their structures and modes of action are different which, in turn, address different purification, detection or therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2, 15, 17, 22 and 23 are generic.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Serial No. 09/938477
Art Unit 1644

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 29, 2003